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| APPLICATION NO.                        | FILING DATE           | FIRST NAMED INVENTOR     | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-----------------------|--------------------------|---------------------|------------------|
| 10/786,429                             | 02/25/2004            | Jay C. Buckey            | DC-0257             | 1958             |
| 7590 02/20/2007<br>Jane Massey Licata  |                       | EXAMINER HUI, SAN MING R |                     |                  |
| Licata & Tyrrell P.C.                  |                       |                          |                     |                  |
| 66 E. Main Street<br>Marlton, NJ 08053 |                       |                          | ART UNIT            | PAPER NUMBER     |
| ,                                      |                       | 1617                     |                     |                  |
| SHORTENED STATUTO                      | RY PERIOD OF RESPONSE | MAIL DATE                | DELIVER             | Y MODE           |
| 3 MONTHS                               |                       | 02/20/2007               | PAPER               |                  |

## Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|  |   | Application No. | Applicant(s)  |  |  |  |
|--|---|-----------------|---------------|--|--|--|
| Office Action Summary  |   | 10/786,429      | BUCKEY ET AL. |  |  |  |
|  |   | Examiner        | Art Unit      |  |  |  |
|  |   | San-ming Hui    | 1617          |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply  |   |                 |               |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                 |               |  |  |  |
| Status   |   |                 |               |  |  |  |
| 1)⊠  | Responsive to communication(s) filed on 21 No   | ovember 2006    |               |  |  |  |
|  | This action is <b>FINAL</b> . 2b) This action is non-final.   |                 |               |  |  |  |
| ′—   |   |                 |               |  |  |  |
| <i>,</i> —   | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.     |                 |               |  |  |  |
| Dispositi  | on of Claims  |                 |               |  |  |  |
| 4)🖂  | Claim(s) 1 is/are pending in the application.   |                 |               |  |  |  |
|  | 4a) Of the above claim(s) is/are withdrawn from consideration.  |                 |               |  |  |  |
|  | i) Claim(s) is/are allowed.   |                 |               |  |  |  |
| 6)⊠  | ⊠ Claim(s) <u>1</u> is/are rejected.  |                 |               |  |  |  |
| 7)   | Claim(s) is/are objected to.  |                 |               |  |  |  |
| 8)[  | 8) Claim(s) are subject to restriction and/or election requirement.                                   |                 |               |  |  |  |
| Applicati  | on Papers   |                 |               |  |  |  |
| 9) The specification is objected to by the Examiner.   |   |                 |               |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.   |   |                 |               |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |                 |               |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |                 |               |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |                 |               |  |  |  |
| Priority u   | ınder 35 U.S.C. § 119   |                 |               |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:   |   |                 |               |  |  |  |
|  | 1. Certified copies of the priority documents have been received.                                     |                 |               |  |  |  |
|  | 2. Certified copies of the priority documents have been received in Application No                    |                 |               |  |  |  |
|  | 3. Copies of the certified copies of the priority documents have been received in this National Stage |                 |               |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |   |                 |               |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |                 |               |  |  |  |
|  |   |                 |               |  |  |  |
| *  |   |                 | •             |  |  |  |
| Attachmen  | t(s)  |                 |               |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  |   |                 |               |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  Notice of Informal Patent Application  |   |                 |               |  |  |  |
| Paper No(s)/Mail Date 6) Other:  |   |                 |               |  |  |  |

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## **DETAILED ACTION**

Applicant's amendments filed November 21, 2006 have been entered. Claims 2-3 have been cancelled. Claim 1 is pending.

The outstanding rejection under 35 USC 112, first paragraph is withdrawn in view of the amendments filed November 21, 2006.

The outstanding rejections under 35 USC 102 are withdrawn in view of the amendments field 21, 2006 as the claim is directed to the use of specific dosage of chlorpheniramine to treat motion sickness.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ueno in view of US 4,624,965 ('965), references of record.

Ueno et al. teaches treatment of S. murinus by administering 20mg/kg of chlorpheniramine in treating motion sickness (see the abstract).

Ueno et al. does not expressly teach the dosage of chlorpheniramine as 12mg.

'965 teaches a method of the similar compounds such as bromopheniramine (structurally analog to chlorpheniramine, only one atom different) studied in Ueno et al., in a low dose, to treat motion sickness (See the abstract, also col. 1-2).

It would have been obvious to one of ordinary skill in the art at the time of invention to employ the instant dose of chlorpheniramine in a method of treating motion sickness.

One of ordinary skill in the art would have been motivated to employ the herein claimed dose of chlorpheniramine in a method of treating motion sickness. It is known that chlorpheniramine as useful and effective in treating motion sickness. It is also known that lowering the dose according to the method of '965 can effective achieve the therapeutic blood level. Therefore, employing chlorpheniramine in the method of '965 to treat motion sickness would therefore be obvious since lowering the dose would also lower the side effect associated with the active agent.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Śan-ming Hul Primary Examiner Art Unit 1617